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General Conditions

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Authority: 15 U.S.C. 3719

Dated: September 9, 2013.

Tanja Popovic,

Deputy Associate Director for Science,
Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS-10199 and CMS-10266]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of

the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *October 15, 2013*:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs Attention: CMS Desk Officer Fax Number: (202) 395-6974 OR Email: OIRA_submission@omb.eop.gov To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Reinstatement without change

of a previously approved collection; *Title of Information Collection:* Data Collection for Medicare Facilities Performing Carotid Artery Stenting with Embolic Protection in Patients at High Risk for Carotid Endarterectomy; *Use:* We provide coverage for carotid artery stenting (CAS) with embolic protection for patients at high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis between 50 percent and 70 percent or have asymptomatic carotid artery stenosis \geq 80 percent in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), a trial under the CMS Clinical Trial Policy (NCD Manual § 310.1, or in accordance with the National Coverage Determination on CAS post approval studies (Medicare NCD Manual 20.7). Accordingly, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the Social Security Act). However, evidence for use of CAS with embolic protection for patients with high risk for carotid endarterectomy and who also have symptomatic carotid artery stenosis \geq 70 percent who are not enrolled in a study or trial is less compelling. To encourage responsible and appropriate use of CAS with embolic protection, we issued a Decision Memo for Carotid Artery Stenting on March 17, 2005, indicating that CAS with embolic protection for symptomatic carotid artery stenosis \geq 70 percent will be covered only if performed in facilities that have been determined to be competent in performing the evaluation, procedure and follow-up necessary to ensure optimal patient outcomes. In accordance with this criteria, we consider coverage for CAS reasonable and necessary (section 1862 (A)(1)(a) of the Social Security Act). *Form Number:* CMS-10199 (OCN: 0938-1011); *Frequency:* Yearly; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 1,000; *Total Annual Responses:* 1,000; *Total Annual Hours:* 500. (For policy questions regarding this collection contact Lori Ashby at 410-786-6322.)

2. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* Conditions of Participation: Requirements for Approval and Reapproval of Transplant Centers to Perform Organ Transplants; *Use:* The Conditions of Participation and accompanying requirements specified in the regulations are used by our surveyors as a basis for determining whether a transplant center qualifies for approval or re-approval under Medicare.

We, along with the healthcare industry, believe that the availability to the facility of the type of records and general content of records is standard medical practice and is necessary in order to ensure the well-being and safety of patients and professional treatment accountability. *Form Number:* CMS-10266 (OCN: 0938-1069); *Frequency:* Yearly; *Affected Public:* Business or other for-profits and Not-for-profit institutions; *Number of Respondents:* 226; *Total Annual Responses:* 528; *Total Annual Hours:* 2,523. (For policy questions regarding this collection contact Diane Corning at 410-786-8486.)

Dated: September 10, 2013.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-9953-PN]

Health Insurance Exchanges; Application by the Accreditation Association for Ambulatory Health Care To Be a Recognized Accrediting Entity for the Accreditation of Qualified Health Plans

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the receipt of an application from the Accreditation Association for Ambulatory Health Care (AAAHC) to be a recognized accrediting entity for the purposes of fulfilling the accreditation requirement as part of qualified health plan (QHP) certification. Regulations require HHS to publish a notice identifying the accrediting entity, summarizing its analysis of whether the accrediting entity meets certain criteria, and providing no less than a 30-day public comment period.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 15, 2013.

ADDRESSES: In commenting, please refer to file code CMS-9953-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. *Electronically.* You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9953-PN, P.O. Box 8010, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-9953-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT: Rebecca Zimmermann, at (301) 492-4396.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of

the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Background

Regulations at 45 CFR 156.275 require qualified health plan (QHP) issuers to be accredited on the basis of local performance of its QHPs by an accrediting entity recognized by the Department of Health and Human Services (HHS). In a final rule published on July 20, 2012,¹ we established the first phase of an intended two-phase approach to recognize accrediting entities and proposed both the National Committee for Quality Assurance (NCQA) and URAC as recognized accrediting entities. On November 23, 2012, we notified the public that NCQA and URAC had both met the requirements in the final rule to be recognized as an accrediting entity (77 FR 42662 through 42668) and were recognized by the Secretary² as accrediting entities for the purposes of QHP certification.

On February 25, 2013, we published a subsequent final rule title, "Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation (78 FR 1283),"³ which amended § 156.275(c) to establish an application and review process to allow additional

¹ Patient Protection and Affordable Care Act; Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans Final Rule 77 FR 42658, 42662-42668 (July 20, 2012) (45 CFR 156.275(c)).

² Certain authority under the Affordable Care Act has been delegated from the Secretary to the Administrator of CMS., 76 FR 53903 through 53906, (Aug. 30, 2011).

³ Patient Protection and Affordable Care Act; Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation; Final Rule, 78 FR 12834, 12854-12855 (February 25, 2013)(45 CFR 156.275(c)).